## REMARKS

Claims 73-104 are pending. Claims 73, 74, 76, 80-84 and 86 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0104030 to Igaki. Claims 75, 99-101 and 104 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Igaki view of U.S. Patent No. 6,251,136 to Guruwaiya. Claims 73, 74, 76-78, 80-82, 86, 88, 89, 91-93 and 98 stand rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent No. EP 0405284 to Greiner. Claims 75, 90 and 99-104 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view of Guruwaiya. Claim 79 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Igaki in view of U.S. Patent No. 6,670,398 to Edwards. Claims 79 and 95 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view of Edwards. Claims 85 and 97 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view of PCT Publication WO 01/87368 to Mehta. Claim 87 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Igaki in view of U.S. Patent No. 6,299,604 to Ragheb. Claim 87 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view of Ragheb. Claims 81, 83, 84, 86, 93, 94, 96 and 98 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view of Igaki.

Applicants respectfully traverse the §103 rejections for the reasons set forth below.

**Independent Claim 73**

Independent Claim 73 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Igaki. In addition, independent Claim 73 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner.

Claim 73 recites a method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:

immersing an intraluminal prosthesis in a mixture of a carrier fluid and a pharmacological agent, wherein the intraluminal prosthesis comprises non-layered polymeric material;

pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to cause the carrier fluid and pharmacological agent to at least partially penetrate the non-layered polymeric material;

removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and ***the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient***, wherein the concentration gradient defines an elution profile of the pharmacological agent from the non-layered polymeric material when the intraluminal prosthesis is deployed within a body of a subject.

Igaki fails to teach or suggest removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient. In fact, the Action concedes that Igaki fails to teach a drug elutably trapped within polymeric material in a predetermined concentration gradient. (Action, Page 2). However, the Action states that "Igaki teaches that the pressure is gradually exhausted (i.e., removing pressure over a predetermined period of time) in a reaction chamber (i.e., under controlled conditions) and, thus, teaches all the steps as claimed." (Action, Page 3). On this basis, the Action then concludes that, "because the method of Igaki is so similar to the claimed steps, the two methods must necessarily achieve similar results." (Action, Page 3). Applicants respectfully disagree.

Igaki does not teach the same steps nor does it achieve similar results as those of the present invention. The Action cites to paragraph 0062 of Igaki for support for the assertion that

Igaki "teaches all the steps as claimed" and therefore that "the two methods must necessarily achieve the same results." Action, page 3. Paragraph 0062 of Igaki recites:

> Finally, a third valve 31 is opened to exhaust $CO_2$ within the reaction chamber 27 gradually to set the inside of the reaction chamber 27 open to atmosphere. The drug 26 is now **fully impregnated** in the stent 1 to complete the luminal stent according to the present invention.
> (emphasis added)

Thus, a full and fair reading of paragraph 0062 of Igaki fails to show that the steps of Igaki result in a concentration gradient in the polymeric material as taught by the present invention but rather describes a process in which a stent is "fully impregnated" with the drug." Clearly, one of ordinary skill in the art would not interpret this to mean the formation of a predetermined concentration gradient as taught by the present invention. Further, the data presented in Table 3 and in Figures 10 and 11 of Igaki support the conclusion that the methods of Igaki in fact teach that only a single concentration of drug is impregnated in the polymeric material of Igaki. For instance, in Table 3 each example presents only a single concentration of impregnated drug. Furthermore, commenting on the Examples, Igaki states "[i]t has been shown that the quantity of transilast impregnated in the stent depends on the pressure and temperature of the supercritical fluid $CO_2$, and that, in particular, if the temperature at which $CO_2$ is made into a supercritical fluid is high, the quantity of transilast impregnated is increased." (Igaki, Para. 98). No teaching or suggestion is made of controlling such variables as pressure or temperature so as to achieve a concentration gradient in the polymeric material but rather, Igaki describes only increasing or decreasing the absolute amount of drug impregnated in the stent.

In fact, the arguments presented in the Action appear to be based on a conclusion that Igaki inherently teaches removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient as is taught by the present invention. Applicants respectfully submit that, as stated in the M.P.E.P., a reference cannot be relied upon for allegedly inherent teachings to support a rejection under 35 U.S.C. §103. Specifically, it is stated in § 2141.02 of the M.P.E.P., with a citation to *In re Rijckaert*, that

"[o]bviousness cannot be predicated on what is not known at the time an invention was made, even if the inherency of a certain feature is later established." (9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993)). Thus, the use of the Igaki reference for its allegedly inherent teachings as a necessary basis for this obviousness rejection renders the rejection improper and Applicants request that it be withdrawn for at least this reason.

In fact, the only method provided in Igaki for controlling the release time point and quantity of an impregnated drug is via the use of layers of biodegradable polymer material and not via a concentration gradient. Igaki specifically states "[b]y forming a further biodegradable polymer layer on the stent surface, it becomes possible to control the release rate of the drug into the blood, impregnated inside of the stent." (Igaki, Para, 0026). Igaki also states "[b]y providing the layer(s) of the drug-containing biodegradable polymer in this manner, one or more drugs may be impregnated in the stent, and it is possible to permit more strict control of the drug releasing time point or the quantity of the released drug, or different drugs can be released at the desired same time point." (Igaki, Para. 0072). In Paragraph 0067 of Igaki it is further stated "...[f]or delaying the release of the drug impregnated in the stent into the blood vessel, it is also possible to form the layer of the biodegradable polymer material, formed only of the biodegradable polymer...." (Igaki,) Accordingly, Igaki fails to teach or suggest a method of impregnating an interluminal prosthesis comprising removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and ***the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient***, as taught by the present invention. In fact, Applicants submit that the teachings of Igaki of the use of layers for controlling the release time point and quantity of an impregnated drug teaches away from the use concentration gradients.

Applicants note that the Action further states that a predetermined concentration gradient can be zero. (Action, Page 3). Applicants respectfully disagree. One of skill in the art would know that the term gradient is defined as "the rate of regular or graded ascent or descent" and that a "concentration gradient" is defined as "a gradual change in the concentration of solutes in a solution as a function of distance through a solution" (see the dictionary definitions included

herein at Appendix A). Clearly one of ordinary skill in the art would not consider a concentration gradient to be zero.

Thus, one of ordinary skill in the art would not, upon reading Igaki, produce a stent comprising a non-layered polymeric material with a drug concentration gradient in the nonlayered polymeric material. To the contrary, one skilled in the art, upon reading Igaki, would use various layers to accomplish what Applicants accomplish via a concentration gradient. The fact that Igaki utilizes layers to control the time of drug release and the quantity of drug release illustrates that Igaki does not utilize or appreciate utilizing a drug concentration gradient for accomplishing time of drug release and/or quantity of drug release.

Accordingly, Igaki fails to teach or suggest all of the recitations of independent Claim 73. Thus, Applicants respectfully assert that the rejections of independent Claim 73, and all claims depending therefrom, under 35 U.S.C. §103 are overcome.

Greiner, the other primary reference cited in the Action, also fails to teach or suggest removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient. Greiner describes a method of impregnating a catheter, made of polymeric material, with a pharmaceutical. The catheter is immersed into a saturated solution of a pharmaceutical in a solvent. The saturated solution serves as a swelling agent and swells the polymeric material of the catheter. The catheter is contacted with the swelling agent at or near supercritical pressure and temperature of the solvent. The pressure is then reduced from supercritical pressure to release the solvent from the catheter, thereby leaving the pharmaceutical impregnated within the catheter. There is no description or suggestion of removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient.

The Action states that the polymeric material of Greiner would "necessarily have a concentration gradient of the pharmacological agent for substantially the same reasons as

discussed..." (for Igaki). Action, Page 4. Further, the Action states once again that a concentration gradient can be zero. *Id.* Applicants respectfully disagree.

Similar to Igaki, discussed above, Greiner also fails to teach or suggest an intraluminal prosthesis wherein a ***pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient*** as taught by the present invention. In fact, the catheter of the Greiner invention is discussed only in terms of being impregnated with specific concentrations of a drug. Thus, Greiner states that "[t]he catheter is found to contain 25% benzocaine by weight...." (Greiner, Col. 5, Example 1). In Example 2, Greiner states that the catheter "is found to contain 42% benzocaine." Thus, Greiner provides no teaching or suggestion of a concentration **gradient** within a non-layered polymeric material as is taught by the present invention.

Further, contrary to the allegations in the Action, Greiner does not describe removing the pressure over a predeterimined time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient as recited in Claim 73 of the present invention. The Action cites to column 4, lines 2-6 of Greiner wherein it states "[a]fter contacting, the volatile swelling agent is separated from the catheter, leaving the pharmaceutical behind. Because of the volatility of the swelling agents employed, separation is easily accomplished by lowering the pressure." Action, Page 5. The Action then contends that "[t]here must be some control of how fast the rate of pressure changes" (*Id.*) but does not provide any evidence for such a supposition.

As discussed above, a reference cannot be relied upon for allegedly inherent teachings to support a rejection under 35 U.S.C. §103. Thus, the use of the Greiner reference for any allegedly inherent teachings as a necessary basis for this obviousness rejection renders the rejection improper and Applicants request that it be withdrawn for at least this reason.

With regard to dependent Claims 86 and 98 (independent Claim 88 is discussed below), the Action states that the polymeric material can be formed only on the surface. The Action provides no support for this assertion and none can be found in Greiner. Greiner describes a method of impregnating a catheter, made of polymeric material, with a pharmaceutical. The

catheter is immersed into a saturated solution of a pharmaceutical in a solvent. The saturated solution serves as a swelling agent and swells the polymeric material of the catheter. The catheter is contacted with the swelling agent at or near supercritical pressure and temperature of the solvent. The pressure is then reduced from supercritical pressure to release the solvent from the catheter, thereby leaving the pharmaceutical impregnated within the catheter. There is no teaching or suggestion that the polymeric material is a coating on a portion of the intraluminal prosthesis as recited in Claims 86 and 98 of the present invention. Accordingly, dependent Claims 86 and 98 are independently patentable.

Accordingly, Greiner fails to teach or suggest all of the recitations of independent Claim 73. Applicants respectfully assert that the rejections of independent Claim 73, and all claims depending therefrom, under 35 U.S.C. §103, are overcome.

**Independent Claim 88**

Independent Claim 88 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner.

Claim 88 recites a method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:

> immersing an intraluminal prosthesis in a mixture of a carrier fluid and a pharmacological agent, wherein the intraluminal prosthesis comprises non-layered polymeric material;
>
> placing the intraluminal prosthesis within a pressure vessel;
>
> pressurizing the interior of the pressure vessel with an inert gas to a predetermined pressure, wherein the inert gas is selected from the group consisting of helium, nitrogen, and argon;
>
> supplying a mixture of a carrier fluid and a pharmacological agent into the pressure vessel;
>
> exposing the non-layered polymeric material and the mixture of carrier fluid and pharmacological agent in the pressure vessel for a time such that the carrier fluid and pharmacological agent at least partially penetrate the non-layered polymeric material; and
>
> releasing the pressure in the pressure vessel over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient, wherein the concentration gradient defines an elution profile of the pharmacological agent from the

non-layered polymeric material when the intraluminal prosthesis is deployed within a body of a subject.

Greiner, as discussed above, fails to teach or suggest removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration as taught by the presently claimed invention. Thus, for at least the same reason that Greiner fails to teach or suggest all of the recitations of independent Claim 73, as discussed above, Greiner fails to teach or suggest all of the recitations of independent Claim 88. As such, Applicants respectfully assert that the rejections of independent Claim 88, and all claims depending therefrom, under 35 U.S.C. §103 are overcome.

**Independent Claim 99**

Independent Claim 99 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Igaki in view of Guruwaiya. Claim 99 is also rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view of Guruwaiya.

As discussed above, Igaki fails to teach or suggest removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient. In fact, the text and data of Igaki support the conclusion that the methods of Igaki result in a polymeric material comprising a single concentration of drug. (*See,* Igaki, for example, at least, Para. 0026, 0072, 0067, Table 3, Figures 10 and 11). The only method provided by Igaki for controlling the release time point and quantity of an impregnated drug is not via a concentration gradient, but rather via the use of layers of biodegradable polymer material. Igaki specifically states "[b]y providing the layer(s) of the drug-containing biodegradable polymer in this manner, one or more drugs may be impregnated in the stent, and it is possible to permit more strict control of the drug releasing time point or the quantity of the released drug, or different drugs can be released at the desired same time point." (Igaki, Para. 0072). Igaki also describes

retarding the rate of release of a drug impregnated in a stent via the use of a layer of biodegradable polymer material not containing a drug. (Igaki, Para. 0073).

One skilled in the art would not, upon reading Igaki, produce a non-layered stent with a drug concentration gradient in the stent material. To the contrary, one skilled in the art, upon reading Igaki, would use various layers to accomplish what Applicants accomplish via a concentration gradient. The fact that Igaki utilizes layers to control the time of drug release and the quantity of drug release illustrates that Igaki does not utilize or appreciate utilizing a drug concentration gradient for accomplishing time of drug release and/or quantity of drug release.

Greiner, the other primary reference cited in the Office Action, also fails to teach or suggest a drug elutably trapped within non-layered polymeric material in a predetermined concentration gradient as taught by the presently claimed invention. For at least the same reasons that Greiner fails to teach or suggest all of the recitations of independent Claim 73 and 88, as discussed above, Greiner also fails to teach or suggest all of the recitations of independent Claim 99.

The secondary reference, Guruwaiya, fails to remedy the deficiencies of primary references, Igaki and/or Greiner. The Action states that Guruwaiya teaches a method of coating a pharmacological agent on a stent wherein certain portions of the stent are masked during the coating process. (Action, Page 3). The Action then concludes that it would have been obvious to have masked certain portions of the stent of Igaki. (Action, Page 3). The Action further states that Claim 99 is rejected under 35 U.S.C. 103(a) as being unpatenatable over Greiner in view of Guruwaiya, for substantially the same reasons as discussed for Igaki in view of Guywaiya. Applicants respectfully disagree.

Applicants submit that to the extent that the combinations of Igaki and/or Greiner and Guruwaiya teach masking the stent of Igaki and/or Greiner, such combinations fail to teach or suggest the following recitations of independent Claim 99:

> masking portions of an intraluminal prosthesis with a protective layer of material such that the intraluminal prosthesis has first and second unmasked portions, wherein the intraluminal prosthesis comprises non-layered polymeric material;... and
>
> removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material

> and such that an amount of the first pharmacological agent remains elutably trapped within the first unmasked portion in a predetermined concentration gradient and an amount of the second pharmacological agent remains elutably trapped within the second unmasked portion in a predetermined concentration gradient, wherein each concentration gradient defines an elution profile of a respective pharmacological agent from the non-layered polymeric material when the intraluminal prosthesis is deployed within a body of a subject.

Accordingly, Igaki, Greiner and Guruwaiya, alone or in combination, fail to teach or suggest all of the recitations of independent Claim 99. Applicants respectfully assert that the rejections of independent Claim 99, and all claims depending therefrom, under 35 U.S.C. §103 are overcome.

**Dependent Claim 79**

Dependent Claim 79 recites the method of Claim 73, wherein the pharmacological agent comprises everolimus. The Action states that Claim 79 is unpatentable over Igaki in view of Edwards. Applicants respectfully disagree.

As discussed above, Igaki fails to teach or suggest all of the recitations of independent Claim 73. Further, Edwards fails to remedy the deficiencies of Igaki. Edwards simply describes everolimus as a therapeutic drug that can be used to suppress a transplant recipient's immune response. Thus, the cited references, alone or in combination, fail to teach or suggest all of the recitations of the present invention or provide any reasonable expectation of success of achieving the present invention with such a combination. Accordingly, Applicants respectfully submit that the rejection of Claim 79 under 35 U.S.C. §103(a) over Igaki in view of Edwards is overcome and respectfully request its withdrawal.

**Dependent Claims 79 and 95**

Dependent Claim 79 recites the method of Claim 73, wherein the pharmacological agent comprises everolimus. Dependent Claim 95 recites the method of Claim 88, wherein the pharmacological agent comprises everolimus. The Action states that Claims 79 and 95 are unpatentable over Greiner in view of Edwards. Applicants respectfully disagree.

As discussed above, Greiner fails to teach or suggest all of the recitations of the present invention. Further, Edwards fails to remedy the deficiencies of Greiner. Edwards simply describes everolimus is a therapeutic drug that can be used to suppress a transplant recipient's immune response. Thus, the cited references, alone or in combination, fail to teach or suggest all of the recitations of the present invention or provide any reasonable expectation of success of achieving the present invention with such a combination. Accordingly, Applicants respectfully submit that the rejection of Claims 79 and 95 under 35 U.S.C. §103(a) over Greiner in view of Edwards is overcome and respectfully request its withdrawal.

**Dependent Claims 85 and 97**

Dependent Claim 85 recites the method of Claim 73, wherein the non-layered polymeric material is non-erodible. Dependent Claim 97 recites the method of Claim 88, wherein the non-layered polymeric material is non-erodible. The Action states that Claims 85 and 97 are unpatentable over Greiner in view of Mehta. Applicants respectfully disagree.

As discussed above, Greiner fails to teach or even suggest all of the recitations of the present invention. Further, Mehta fails to remedy the deficiencies of Greiner. Mehta simply describes deposition of a coating by altering the temperature and pressure of a SCF in which a drug or polymer to be coated is dissolved. Thus, the cited references, alone or in combination, fail to teach or suggest all of the recitations of the present invention or provide any reasonable expectation of success of achieving the present invention with such a combination. Accordingly, Applicants respectfully submit that the rejection of Claims 85 and 97 under 35 U.S.C. §103(a) over Greiner in view of Mehta is overcome and respectfully request its withdrawal.

**Dependent Claim 87**

Dependent Claim 87 recites the method of Claim 73, further comprising immersing the intraluminal prosthesis in a mixture of a carrier fluid and radiopaque material; and pressurizing the mixture of carrier fluid and radiopaque material for a time sufficient to cause the carrier fluid and radiopaque material to at least partially penetrate the non-layered polymeric material. The Action states that Claim 87 is unpatentable over Igaki in view of Ragheb. The Action further

states that Claim 87 is unpatentable over Greiner in view of Ragheb. Applicants respectfully disagree.

As discussed above, Igaki and Greiner fail to teach or even suggest all of the recitations of independent Claim 73. Further, Ragheb fails to remedy the deficiencies of Igaki. Ragheb simply describes radiopaque agents as alternative bioactive materials that can be used in the vascular system. Thus, the cited references, alone or in combination, fail to teach or suggest all of the recitations of the present invention or provide any reasonable expectation of success of achieving the present invention with such a combination. Accordingly, Applicants respectfully submit that the rejections of Claim 87 under 35 U.S.C. §103(a) over Igaki in view of Ragheb and over Greiner in view of Ragheb are overcome and respectfully request their withdrawal.

**Dependent Claims 81, 83, 84, 86, 93, 94, 96 and 98**

Dependent Claim 81 recites the methods of Claims 73, 76, and 80, wherein the carbon dioxide contains one or more of a co-solvent, a surfactant, and a co-surfactant. Dependent Claim 83 recites the methods of Claims 73, 76, 80 and 81, wherein the co-solvent is selected from the group consisting of ethanol and methanol. Dependent Claim 84 recites the method of Claim 73, wherein the intraluminal prosthesis is a stent. Dependent Claim 86 recites the method of Claim 73, wherein the non-layered polymeric material is a coating on a portion of the intraluminal prosthesis. Dependent Claim 93 recites the methods of Claims 88 and 91, wherein the carbon dioxide contains one or more of a co-solvent, a surfactant, and a co-surfactant. Dependent Claim 94 recites the methods of Claims 88, 91 and 93, wherein the co-solvent is selected from the group consisting of ethanol and methanol. Dependent Claim 96 recites the method of Claim 88, wherein the intraluminal prosthesis is a stent. Dependent Claim 98 recites the method of Claim 88, wherein the non-layered polymeric material is a coating on a portion of the intraluminal prosthesis. The Action states that dependent Claims 81, 83, 84, 86, 93, 94, 96 and 98 are allegedly unpatentable over Greiner in view of Igaki. Applicants respectfully disagree.

As discussed above, Igaki and Greiner fail to teach or suggest all of the recitations of independent Claims 73 and 88. Thus, Igaki and Greiner, alone or in combination, fail to teach or suggest all of the recitations of the present invention or provide any expectation of success in

such a combination. Accordingly, Applicants respectfully submit that the rejections of dependent Claims 81, 83, 84, 86, 93, 94, 96 and 98 under 35 U.S.C. §103(a) over Igaki in view of Ragheb and over Greiner in view of Ragheb are overcome and respectfully request their withdrawal.

**Conclusion**

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

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Anthony DeRosa